

AUG 8 2012

**510(k) Summary**  
**per 21 CFR §807.92**

**Submitter's  
Name and  
Address**

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**Contact Name  
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**Date Prepared**

08 August, 2012

**Proprietary  
Name**

Convey™ Guiding Catheter

**Common Name**

Percutaneous Catheter

**Classification**

Class II, 21 CFR Part 870.1250

**Review Panel**

Cardiovascular

**Product Code**

DQY

**Product  
Definition**

A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

**Predicate  
Devices**

Medtronic Launcher™ Guide Catheter (6F)	K021256	17 May 2002
Medtronic Launcher™ Guide Catheter (5F)	K030779	24 April 2003

**Device  
Description**

The guiding catheter is a flexible plastic tube featuring a luer hub, a strain relief, a body, an intermediate tip, and a soft tip. The body and the intermediate tip exist of an inner liner (basecoat) and a outer jacket (topcoat) reinforced with a tightly wound stainless steel braid wire in between the layers. The central lumen of the catheter is used for the percutaneous, transluminal passage and placement of guidewires, diagnostic and therapeutic devices within the vascular system. After the catheter is inserted through the skin using a dilator, a sheath (introducer) and a guide wire it is brought into position. Subsequently, a guidewire is advanced through its lumen and tracked over by a diagnostic device (angiographic catheter, IVUS-catheter) and/or a therapeutic device (e.g., balloon dilatation catheter, stent and delivery system, embolization device) to the intended location. The distal section of the catheter has a variety of preformed shapes (e.g., Judkins Left (abbreviated as JL), Judkins Right (JR), Amplatz (AL), Multi-purpose, hockey stick) to facilitate placement of the catheter tip in the desired target vessel. Some catheter models feature two (2)

small "in-line" side holes in the intermediate tip section to maintain perfusion of the target vessel. This device is a single-use device (i.e., single patient, single procedure, single purpose use). After finalizing the procedure, the catheter is withdrawn, removed and discarded. The intravascular guiding catheter is a cardiovascular catheter with GMDN-code 17846 (and ECRI-code 17846) with GMDN definition: A flexible tube with a central lumen used for the percutaneous, transluminal passage and placement of guidewires and diagnostic and therapeutic devices within the vascular system. After the tube is inserted in position, a guidewire is advanced through its lumen and tracked over by a diagnostic / therapeutic device (e.g., balloon dilatation catheter, stent and delivery system, or embolization device) to the intended location. The distal section of the tube can have a variety of preformed shapes (e.g., straight, multi-purpose, hockey stick, renal double curve); This is a single-use device. (Reference [www.GMDNagency.org](http://www.GMDNagency.org)).

**Intended Use of Device**

The **Convey** Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Convey Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

**Indications for Use**

The **Convey** Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The **Convey** Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

**Comparison of Technological Characteristics**

The Convey™ 5F Guiding Catheter and Convey™ 6F Guiding Catheter incorporate substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices, the Medtronic Launcher 6F Guide Catheter (K021256) and the Medtronic Launcher 5F Guide Catheter (K030779).

**Comparison to Predicate Devices Characteristics**

<b>Convey Characteristic</b>	<b>Medtronic Launcher 5F &amp; 6F</b>
Diameters 5F and 6F	Same diameters serving same function.
Effective Length 100cm	Same length .
Side holes 0 or 2	Same
Various pre-shaped distal catheter tip shape configurations that enable proper catheter positioning in target vessel	Equivalent distal catheter tip shapes
Atraumatic distal soft tip	Similar distal soft tip and same function.

**Comparison of  
Technological  
Characteristics  
(Continued)**

**Comparison to Predicate Devices in Materials and Manufacturing**

<b>Convey Characteristic</b>	<b>Medtronic Launcher 5F &amp; 6F</b>
Luer Hub	Similar design and material serving same function.
Strain Relief	Similar design and material serving same function.
Body basecoat (inner liner)	Similar design and material and serving same function.
Braiding between base and top coat	Same design and material serving same function.
Body topcoat (outer jacket)	Similar design and material and serving same function.
Polymer coating on top coat for smooth guiding catheter introduction	Lubricious layer not present at top coat of predicate devices
Intermediate tip	Similar design and material serving same function.
Soft tip	Similar designs with similar material serving same function.
Manufacturing Methods	Similar methods (catheter extrusion, catheter distal tip shaping, packaging)
Intended use	Same
Operating principle	Same
Sterilization Method	Same method (EtO sterilization)
Single use device	same
SAL	Same level of assurance.
Packaging process and design	Similar process and design ( catheter positioned on mounting card in sterile barrier pouch together with an IFU in carton box)

## Performance Data

Substantial Equivalence of the Convey™ Guiding Catheter with the predicate devices has been demonstrated via data collected from non-clinical design verification tests and two European clinical post market surveillance (comparison) studies (design validation). Biocompatibility of the device was tested in several biological evaluation tests completed per current ISO 10993-series of standards.

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following **biocompatibility tests** were completed on the Convey™ Guiding Catheter considering Categorization per Material Characterization for Medical Application per ISO 10993-1 and USP.

Categorization by **Nature** of body contact:

- External Communicating Device:
- Circulating blood: devices that contact circulating blood

Categorization by **Duration** of Contact:

- Limited Exposure (A): devices whose single or multiple use or contact is likely to be up to 24 h.

ISO 10993-4: Haemocompatibility:

- Hemolysis
- In vitro Haemocompatibility
- Coagulation Tests Prothrombin Time Assay (PT)
- Coagulation Unactivated Partial Thromboplastin Time Assay (UPTT).

ISO 10993-5: Cytotoxicity – MEM-elution (USP<87>)

ISO 10993-7: Ethylene Oxide Sterilization Residuals

ISO 10993-10: Sensitization (USP<1184>)

ISO 10993-10: Irritation / Intracutaneous Reactivity (USP <88>)

ISO 10993-11: Acute Systemic Toxicity (USP <88>)

ISO 10993-11: Material Mediated Pyrogenicity (USP <35>)

USP <661>: Packaging Plastic Containers Leachables

**Additional USP tests conducted:**

USP <85> Endotoxin-Mediated Pyrogenicity

USP <788> Particulate testing (light obscuration) (after simulated use)

The following in-vitro performance tests (following simulated use, if applicable) were completed of the Convey™ Guiding Catheter:

- Shape Conformance (Shape retention)
- Inner Diameter
- Outer Diameter
- Catheter Usable Length
- Coating Length
- C-Kink (Bending Kink Diameter)
- Euler Kink (Axial Kink Displacement)
- Radial Stiffness (Collapse)
- Coating Integrity (Visual Inspection)
- Outer Friction & Wear (Coating Integrity – functional test)
- Three Point Bending Test (Bending Stiffness Body)
- Pull Force (after simulated use)
- Radiopacity
- Torque Strength

**Conclusion**

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In summary, the subject PendraCare's Convey™ 5F Guiding Catheter and Convey™ 6F Guiding Catheter are substantial equivalent to the predicate devices Medtronic's 5F Launcher Guide Catheter (#K030779 dated April 24, 2003)] and Medtronic's 6F Launcher Guide Catheter (# K021256 dated May 17, 2002) with respect to the intended use, operating principles, fundamental design, catheter dimensions, materials, technology, packaging, labeling and sterility.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

AUG 8 2012

PendraCare International B.V.  
c/o Corvitex Corporation  
Tom Nolan  
Managing Director  
7205 Laketree Drive  
Raleigh, North Carolina 27615

Re: K120585  
Trade/Device Name: Convey™ 5F Guiding Catheter; Convey™ 6F Guiding Catheter  
Regulatory Number: 21 CFR Part 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: II (two)  
Product Code: 74 DQY  
Dated: July 30, 2012  
Received: July 31, 2012

Dear Mr. Nolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): **K120585**

Device Name:           Convey™ 5F Guiding Catheter,  
                              Convey™ 6F Guiding Catheter

#### Indications for Use:

The Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*M. G. Hilleman*

(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number   K120585